

### **REMARKS/ARGUMENTS**

In response to the Office Action mailed July 27, 2004, Applicants amend their application and request reconsideration in view of the amendments. In this amendment, Claims 37 and 41 are amended, Claims 38, 39, 40, 43, 45 and 46 are cancelled without prejudice and no claims have been added so that Claims 37, 41 and 42 are currently pending. No new matter has been introduced.

Claims 37-40 and 46 were rejected as being anticipated by U.S. Patent Number 5,993,481 to Marcade et al. (Marcade). This rejection is respectfully traversed.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention as claimed in amended independent Claim 37 is directed to a graft system. The graft system comprises a one-piece tubular graft component having three portions or regions. The middle portion includes a plurality of independent gripping stents configured to prevent migration of the graft. The first end portion includes an aortic stent having an O-shaped portion and a D-shaped portion. The second portion includes an iliac stent. The cross-sectional areas of the D-shaped portion and the iliac stent are greater than the middle portion.

Marcade discloses modular bifurcated intraluminal grafts. The modular system includes a base member and one or more grafts connected thereto. More specifically, the specification defines the term "modular" as referring to the fact that the system includes a number of individual components, which may be separately delivered by intraluminal techniques to the aneurysm site and then interconnected with one another *in situ* to form the bifurcated graft. In one embodiment, the modular system includes a primary graft, a base member and first and second grafts. The primary graft includes a main tapered portion and an annular sleeve. The first and second grafts comprise generally cylindrical tubular constructions. The base member is

a hollow generally Y-shaped structure formed by a frustoconical main body which branches into two legs. Each of the grafts consist of an outer layer which is supported along substantially its entire length by an expandable stent. It is specifically disclosed that the outer graft layer is substantially tubular, but can be made tapered. The stent in this embodiment may be self-expanding. The base member is similar in construction to the grafts and includes a flexible outer layer. In another embodiment, the base member has a generally frustoconical main body which gradually decreases in diameter from its distal end to its juncture with an annular sleeve. The main body of the base member is divided into two portions by a web. As with the first embodiment described the base member consists of a flexible outer layer which is supported internally along its entire length by an expandable stent. In yet another alternate embodiment, the base member has a substantially uniform diameter for a major portion of its overall length. The diameter of the base member then gradually increases in a second region. The base member includes a stitch line, which extends in the longitudinal direction in the first region. The stitch line joining the outer layer on the diametrically opposed surfaces of the base member to define two tubular channels. The support stent for this base member may consist of an assembly of several members which independently support the tapered region, tubular channels and the uniform diameter region.

Marcade fails to disclose or even remotely suggest a graft system having an aortic stent with an O-shaped region and a D-shaped region. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested. Claim 46 has been cancelled without prejudice.

Claims 41-43 and 45 were rejected as being unpatentable over Marcade in view of U.S. Patent No. 6,123,722 to Fogarty et al. (Fogarty). This rejection is respectfully traversed.

U.S. Patent No. 6,123,722 to Fogarty et al. discloses stents and stent-grafts for the treatment of aneurysms. Specifically, Fogarty discloses prosthetic modules, which may be selectively combined to form a composite prosthesis. Also disclosed is a delivery catheter which comprises a tubular cover and a shaft coaxially positioned in the cover. The catheter also comprises a plurality of runners and a nosecone.

Fogarty, as the Examiner suggests, does disclose a bellows like structure. However, Fogarty fails to disclose or even remotely suggest the structure as claimed in amended independent Claim 37. Therefore, neither reference, whether taken alone or in combination, teaches or discloses all of the claimed elements. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 37-43 and 45-46 were rejected as being unpatentable over Fogarty in view of Marcade. This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant’s disclosure. In *re* Vaack, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.”

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). “All

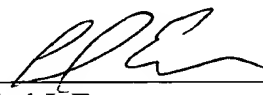
words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).”

For the reasons set forth above, Applicants respectfully submit that the references, whether taken alone or in combination, fail to disclose or suggest the claimed invention as amended. In addition, there is no motivation to combine the references. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

A favorable Action on the merits is earnestly solicited.

Respectfully submitted,

By: \_\_\_\_\_

  
Carl J. Evens  
Reg. No. 33,874

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2518  
Dated: October 20, 2004